

**REMARKS**

1. Applicant thanks the Examiner for his findings and conclusions.
- 5 2. It should be appreciated that the Applicant has elected to amend Claims 1-6, 8, 9, 12, 16, 17, and 21-25 and to cancel Claims 7, 18-20, and 27 solely for the purpose of expediting the patent process in a manner consistent with the PTO's Patent Business Goals, 65 Fed. Reg. 54603 (9/8/00). In making such amendments, Applicant has not and does not in any way narrow the scope of protection to which the Applicant considers the invention herein entitled. Rather, 10 Applicant reserves Applicant's right to pursue such protection at a later point in time and merely seeks to pursue protection for the subject matter presented in this submission.

15 **Hilton Davis / Festo Statement**

The amendments herein were not made for any reason related to patentability. Claims 1-6, 8, 9, 12, 16, 17, and 21-24 were amended to clarify the invention. Claim 25 was separated into two claims. All of the above listed amendments were made for reasons other than patentability.

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3. Claims 1-22 and 25-27 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

**Claims 1-22 and 25-27**

- 25 The Applicant amends Claim 1 in order to clarify that the invention has a useful result by further requiring that the step of classifying the subject classifies the subject into a state of glucose metabolism disorder. Support for the amendment is found in the Application as filed at least at page 11, lines 3-17; page 4, lines 25-30; and page 5, lines 11-13. Screening a subject for any biomedical disorder 30 is a useful result as evidenced by a multi-billion dollar field devoted to testing for

medical disorders. In this case, Claim 1 as amended is still more specific requiring the useful result of classifying a subject into a state of metabolism disorder, such as being diabetic, pre-diabetic, normal, or being hyperinsulinemic. Accordingly, the rejection of Claims 1-22 and 25-27 under 35 U.S.C. § 101 as 5 being directed to non-statutory subject matter is deemed to be overcome.

4. Claims 1-27 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

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### **Claim 1**

As to Claim 1, the Examiner states the term "shape" is vague and indefinite. The Applicant amends Claim 1 in order to remove the term shape from Claim 1. Accordingly, the rejection of Claim 1 and all claims dependent therefrom under 15 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention is deemed to be overcome.

### **Claim 1**

20 Claim 1 is objected to by the Examiner as having improper antecedent basis for the clauses "said plurality of glucose values" and "said profile". For both cases, the Applicant amends Claim 1 to remove the cited clauses. Accordingly, the rejection of Claim 1 and all claims dependent therefrom under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and 25 distinctly claim the subject matter which the Applicant regards as the invention is deemed to be overcome.

### **Claims 17-20**

The Applicant amends Claim 17 in order to clarify the invention by further 30 defining  $P_1$  as a first parameter, the first parameter comprising glucose

concentration,  $P_2$  as a second parameter, the second parameter comprising rate at which glucose concentration rises,  $P_3$  as a third parameter, the third parameter comprising maximum monitored glucose concentration;  $P_4$  as a fourth parameter, the fourth parameter comprising duration that glucose remains elevated;  $P_5$  as a fifth parameter, the fifth parameter comprising rate of decrease of glucose concentration after a peak; and  $P_6$  as a sixth parameter, the sixth parameter comprising minimum glucose concentration after a maximum; and wherein  $W_1$ ,  $W_2$ ,  $W_3$ ,  $W_4$ ,  $W_5$ ,  $W_6$ , are weighting factors, wherein at least two of said weighting factors are non-zero. Further, in order to expedite the patent prosecution process, the Applicant cancels Claims 18-20. Accordingly, the rejection of Claims 17-20 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention is deemed to be overcome.

- 15 5. Claims 1-13, 16, and 21-27 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. patent no. 6,925,393 (hereinafter "Kalatz").

The Applicant amends Claim 1 in order to distinguish Claim 1 from the cited art by further requiring Claim 1 to generate a screening factor where the screening factor comprises a mathematical representation of at least a plurality of glucose concentrations within the glucose concentration profile, where the screening factor is uniquely associated with a state of glucose metabolism disorder, and where the state of glucose metabolism disorder includes any of: diabetic, pre-diabetic, normal, and hyperinsulinemic. Still further, the Applicant amends Claim 25 1 to clarify that the classifying step classifies the subject into one of the states of glucose metabolism disorder based on evaluation of the screening factor. Support for the amendment is found in the specification as filed at least at page 9, lines 1-7, 9-11, and 23; Figure 2; and page 11, lines 3-17; page 4, lines 25-30; page 5, lines 11-13; and page 25, line 4 to page 26, line 31. In stark contrast, 30 Kalatz does not teach or suggest the use of a screening factor used to classify a subject into a state of metabolism disorder where the metabolism disorder is any of diabetic, pre-diabetic, normal, and hyperinsulinemic. Accordingly, the rejection

of Claims 1-13, 16, and 21-27 under 35 U.S.C. § 102(e) as being anticipated by Kalatz is deemed to be overcome.

5 The Applicant further amends Claim 1 to correct a grammatical error in the preamble and to clarify that the glucose profile is a glucose concentration profile.

As a result of amendments to parent Claim 1, the Applicant amends Claims 2-6, 8, 9, 12, 17, and 21-24 as detailed, *infra*.

**Claims 2-4**

10 The Applicant amends Claims 2-4 to conform descendent language with antecedent language usage and further amends Claims 3 and 4 in order to conform with standard claim drafting practices.

**Claims 5, 6, 8, 9, 16, 17, 21, and 22**

15 The Applicant amends Claims 5, 6, 8, 9, 16, 17, 21, and 22 to conform language usage with that of amended Claim 1 according to standard claim drafting practices.

**Claims 16 and 17**

20 The Applicant further amends Claims 16 and 17 to depend directly from parent Claim 1.

**Claims 12, 23, and 24**

25 The Applicant amends Claims 12, 23, and 24 to conform with standard claim drafting practices.

**Claim 7**

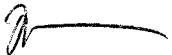
The Applicant cancels Claim 7 from the Application.

6. Claim 25 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Kalatz in view of U.S. patent no. 6,853,854 (hereinafter "Proniewicz").
- 5 In view of the above described amendments, the current rejection of Claim 25 under 35 U.S.C. § 103(a) as being unpatentable over Kalatz in view of Proniewicz is rendered moot.
- 10 7. Claims 1 and 27 stand provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of Claim 1 of copending patent application no. 10/702,710. As amended, Claim 1 is no longer coextensive in scope with that of Claim 1 of copending patent application no. 10/702,710. Claim 27 is cancelled from the Application. Accordingly, the rejection of Claims 1 and 27 under 35 U.S.C. § 101 as claiming the same invention as that of Claim 1 of copending patent application no. 10/702,710 is deemed to be overcome.
- 15 8. The Applicant amends Claim 25 and adds new Claim 28 to separate the claim elements into two claims and to conform descendent language with antecedent language usage according to standard claim drafting practices.
- 20 Support for new Claim 28 is found at least within original Claim 25.
- 25 9. New Claims 29-33 are added to the Application. Support for new Claims 29-33 is found in the Application as filed at least at page 9, lines 9-11; page 16, lines 12-22; page 22, line 25 to page 23, line 21; and page 25, line 30 to page 26, line 14. The Applicant certifies that no new matter was added by way of the new Claims.

**CONCLUSION**

In view of the above, the Application is deemed to be in allowable condition. The Examiner is therefore earnestly requested to withdraw all outstanding rejections, allowing the Application to pass to issue as a United States Patent. Should the  
5 Examiner have any questions regarding the application, he is respectfully urged to contact Applicant's attorney at (650) 474-8400.

Respectfully submitted,



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